



UNIVERSITÀ  
DEGLI STUDI DI MILANO-BICOCCA

## SYLLABUS DEL CORSO

### Study design: Ethics, Regulatory and Statistical Aspects

2405-1002-04

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#### Obiettivi

##### *Statistical Aspects*

To understand the different types of studies in clinical research: a translational approach from pre-clinical to clinical research.

##### *Research Ethics*

To provide students with an overview of the main ethical and legal issues related to scientific research, access to data and data sharing. The Research Ethics course is designed in a highly innovative manner, with the goal of fostering an ethical attitude in the relationship with the patients and/or the lab animals (research ethics and animal ethics) and with the colleagues (research integrity).

##### *Regulatory Aspects*

Introduction to the key features relating to the regulatory legislation and the Good Clinical Practices (GCP) principles.

#### Contenuti sintetici

##### *Statistical Aspects*

Design of RCTs – 6h Maria Grazia Valsecchi

Early phase study design – 4h Stefania Galimberti

Biomarker based designs – 4h Andrea Callegaro

Multiple testing – 2h Aldo Solari

Sample Size Calculation – 2h Davide Bernasconi

Adaptive designs – 4h Federico Rotolo

Estimands – 2h Stefano Vezzoli

Bayesian designs – 4h Paola Berchiolla

Study PASS (Post Authorization Safety Study) and PAES (Post Authorization Efficacy Study) – 4h Domenico

Criscuolo

#### *Research Ethics*

Fundamental ethics principles in research; Data governance and regulatory landscape (GDPR); issues and models related to data access / data sharing – 2h Luca Marelli

The Ethics and Law of Experiments on Animals; End of life issues and the rights of terminally ill patients – 2h Silvia Salardi

The role of Ethical Committees – 2h Maddalena Lettino

#### *Regulatory Aspects*

Regulatory aspects & legislations: the view of AIFA – 2h Sandra Petraglia

Regulatory aspects & legislations: the view of pharma – 2h Maria Elena Trovati

Regulatory aspects & legislations in the area of rare-diseases – 2h Annabella Amatulli

Good clinical practices – 2h Silvia Mori

## **Programma esteso**

### **Prerequisiti**

### **Modalità didattica**

### **Materiale didattico**

### **Periodo di erogazione dell'insegnamento**

#### *Statistical Aspects*

June 21st 17.00-19.00 Maria Grazia Valsecchi - PRE-RECORDED VIDEO

June 22nd 9.00-13.00 Maria Grazia Valsecchi - PRE-RECORDED VIDEO

June 26th 17.00-19.00 Andrea Callegaro - STREAMING

June 28th 17.00-19.00 Andrea Callegaro - STREAMING

June 29th 9.00-13.00 Stefania Galimberti - PRE-RECORDED VIDEO

July 1st 17.00-19.00 Aldo Solari - STREAMING

July 3rd 17.00-19.00 Davide Bernasconi - PRE-RECORDED VIDEO

July 5th 17.00-19.00 Stefano Vezzoli - STREAMING

July 6th 9.00-13.00 Federico Rotolo - PRE-RECORDED VIDEO

July 10th 17.00-19.00 Paola Berchialla - PRE-RECORDED VIDEO

July 12th 17.00-19.00 Paola Berchialla - PRE-RECORDED VIDEO

July 13th 9.00-13.00 Domenico Criscuolo - STREAMING

#### *Research Ethics*

July 15th 17.00-19.00 Luca Marelli - STREAMING

July 17th 17.00-19.00 Silvia Salardi - STREAMING

July 19th 17.00-19.00 Maddalena Lettino - STREAMING

#### *Regulatory Aspects*

July 22nd 17.00-19.00 Sandra Petraglia - STREAMING

July 24th 17.00-19.00 Silvia Mori - STREAMING

July 26th 17.00-19.00 Maria Elena Trovati - STREAMING  
July 27th 10.00-12.00 Annabella Amatulli - STREAMING

**COURSE EVALUATION:** September 11th 17.00-18.00

### **Modalità di verifica del profitto e valutazione**

Individual assignment - Multiple choice questions

### **Orario di ricevimento**

### **Sustainable Development Goals**

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